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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,551	02/27/2002	Jose L. Boycr	03678.0103.CPUS00	6893

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/19/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,551	BOYER ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1 in Paper No. 11 dated July 9, 2003 is acknowledged.

2. Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11 dated July 9, 2003.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing intraocular pressure comprising the administration of uridine 5'-diphosphae-α-D-glucose, does not reasonably provide enablement for a method of reducing intraocular pressure comprising the administration of any compound of Formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974).

The instant specification is drawn to a method of reducing intraocular pressure. The method comprises administering to a subject a pharmaceutical composition comprising an effective amount of a nucleoside 5'-pyrophosphate pyranoside or analogue, which is defined by general Formula I. Each of the terms "alkyl", "cycloalkyl", "arylalkyl", "aryl", "arylalkenyl", "heterocycle of 5 to 7 members", "heterocyclic ring of 5 to 7 members", "an amino acid radical", and "a peptide radical comprising 2 to 10 amino acid units" lack support wherein applicants fail to provide a written description which teaches how to make and use same in a process for preparing the nucleoside 5'-pyrophosphate pyranoside or where applicants fail to teach how to use same incorporated into an pharmaceutical composition used to reduce intraocular pressure. While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention. A broad claim requires a correlatively broad and sufficient disclosure to support it.

Presently, the only example in the specification is drawn to effects of uridine 5'-diphosphae-α-D-glucose on intraocular pressure. Applicants do not provide an adequate written description which provides guidance for the preparation of compounds

within the scope of Formula I. Applicants do not provide an adequate written description which provides guidance for the use of compounds within the scope of Formula I in intraocular pressure reduction applications. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. The process is considered to be incomplete wherein applicants set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms (e.g. all moieties described as "an amino acid radical" wherein the identity of said radical is not set forth in any synthetic procedural steps or any specific compound containing same is utilized in any specific method).

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400. The factors include: 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art, and 7) the breadth of the claims.

With regard to factors one and two cited above the quantity of experimentation needed to determine the specific chemical formula of the active ingredient, the amount of experimentation needed to determine the amount of an efficacious amount for the

reduction of intraocular pressure and the time table necessary to achieve efficacious administration would impose an undue burden upon the skilled artisan. There has not been provided adequate guidance in the written description for preparing compounds of Formula I or using same commensurate in scope with applicant's claims.

With regard to factors four, five and six, it is noted that there is a great deal of unpredictability in the pharmaceutical/treatment arts. The specification provides no evidence that the compounds of Formula I, other than uridine 5'-diphosphae-α-D-glucose, are able to reduce intraocular pressure. The specification only hints at how the skilled artisan would assess whether or not a given nucleoside might be able to effectively treat a subject in need of reduction of his/her intraocular pressure. The guidance provided by the specification amounts to an invitation to the skilled artisan to try and follow the disclosed instructions to make the claimed nucleosides which might work to reduce intraocular pressure. It is noted that the data obtained from the uridine 5'-diphosphae-α-D-glucose examples in seen to be insufficient to provide adequate support for compounds of Formula I as broadly claimed or for their use in the instantly claimed method.

Given that the treatment of ophthalmic conditions is unpredictable and the results depend on numerous known and unknown parameters such as the chemical composition employed in the treatment regimen; given the lack of examples and guidance provided in the specification demonstrating that compounds of Formula I other than uridine 5'-diphosphae-α-D-glucose as broadly claimed are able to reduce

intraocular pressure, the specification is not enabled for the instant invention as broadly claimed.

Conclusion

5. Yerxa et al. U.S. Patent 6,323,187 (Yerxa) is seen as the closest prior art. Yerxa teaches the tetraphosphate compounds of Formula I. Yerxa teaches that esters and amides of the compound of Formula I are useful for treating ophthalmic disorders such as dry eye and retinal detachment. They are also useful for increasing drainage of the lacrimal system. The compounds may be administered orally, topically, parenterally, by inhalation or spray, or intra-operatively.

6. Claims 1-18 are pending. Claims 11-18 are withdrawn from consideration as being drawn to a nonelected invention. Claims 1-10 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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